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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CR-18-00258-EJD JOINT STATUS MEMORANDUM

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for October 2, 2019. Statements from the government (Section I) and from the defense (Section II) are set forth below.

I. Government's Statement

A. Background Regarding Defendant's Motion and Agency Documents

After Defendants filed their Motion to Compel production of documents from FDA and CMS (Dkt. No. 67), the parties briefed the matter, and the Court received information from FDA and CMS themselves. As explained in the government's briefing, Defendants' Motion turns on the proper scope

of the government's discovery obligations. Defendants do not contest that those obligations apply only where the prosecution has access to the materials in question. Here, the prosecution has shown that it lacks access to the documents identified in Defendants' Motion—documents which are in the possession, custody, and control of FDA and CMS themselves. That fact means that those materials are not covered by the government's obligations under Rule 16 and *Brady*. Nonetheless, the government has never objected to Defendants obtaining these materials. Thus, on May 9, 2019, the government sent written requests to FDA and CMS asking for all of the document categories listed in Defendants' filing. In response, the agencies noted the challenges associated with providing those documents, but agreed to produce them.

Specifically, on July 9, 2019, FDA sent a letter to counsel for the government and for Defendants confirming that it was "working diligently to collect, process, review, and ultimately produce all documents responsive to all six categories requested by the parties." (Dkt. No. 89-2). On July 12, 2019, CMS sent a similar letter to the parties restating its agreement to produce documents in its possession responsive to the categories included in the government's written request. (Dkt. No. 89-3).

After reviewing the agencies' submissions, the Court issued an order on July 19, 2019 directing FDA and CMS to produce responsive materials. (Dkt. No. 111). The Court's Order acknowledged the agencies' cooperation and noted their agreements to produce. Although the Court did not accept the agencies' proposed timelines for production, it took the agencies at their word that they would diligently search for and produce the responsive documents. *Id.* Regarding timing, the Court ordered the agencies to complete their productions no later than October 2, 2019 and to advise the parties by September 23, 2019 whether they anticipated completing their productions by the deadline.

B. Production Progress Since the Court's Order

The government forwarded the Court's July 19 order to the agencies and discussed the requirements with agency counsel. The agencies reiterated their intentions to produce responsive documents and indicated that they would produce on a rolling basis, allowing the parties to monitor the progress of their productions. Contemporaneously, the government secured a waiver from the Theranos assignee allowing disclosure of Theranos information. The government had previously drafted and negotiated a stipulated protective order addressing the agencies' other stated concerns.

After completing significant portions of their productions, the agencies concluded that their reviews could be further expedited if the Court entered an additional protective order providing that the production of FDA and CMS documents would not constitute waivers of the agencies' privileges or protections. The government subsequently negotiated such a protective order with Defendants, and the Court entered the order on September 17, 2019. (Dkt. No. 120). The agencies' productions then proceeded as contemplated, with FDA and CMS making a combined six productions to the parties. The agencies made their productions to Defendants directly to avoid unnecessary delay.

On September 23, 2019, FDA and CMS sent letters to government counsel providing updates regarding their respective productions. The letter from CMS is attached hereto as **Exhibit A**. FDA's letter is attached as **Exhibit B**. As stated in its letter, CMS is on track to produce all responsive, non-privileged documents by the October 2 deadline or shortly thereafter. CMS's total document production will consist of nearly 14,000 documents, and the final portion of that production is currently being processed by DOJ's Litigation Technology Service Center on the East Coast.

As to FDA, the agency expects to be in substantial compliance with the Court's order as of October 2. To date, FDA has collected more than 150,000 documents and made four productions to the parties totaling more than 25,000 pages. That progress was achieved thanks to a special arrangement with FDA's parent agency allowing for use of an electronic document review platform. As explained in the letter, approximately half of the documents collected by FDA in response to these requests were determined through metadata to be duplicative of FDA's previous productions, which all parties have received. Of the remaining documents, FDA subsequently used textual analysis to identify another 40,000 documents as potential duplicative, and are currently working to confirm that those documents are indeed duplicates. That review is mostly complete. The government understands that, by approximately October 2, 2019, FDA will have completed its review and production of documents not flagged as duplicates, such that Defendants will have received the vast majority if not all of the information responsive to their requests. The FDA's remaining tasks are to complete its review of likely duplicative documents and continue attempts to resolve some technical issues it has encountered. It reports that it will need less than one month to complete those tasks, and that this additional work is unlikely to lead to the production of novel information.

C. Defendants' Complaints

On September 25, 2019, the parties met and conferred regarding the current status of the agencies' document productions. During that conversation, defense counsel expressed dissatisfaction with certain aspects of the agencies' productions. Defendants' complaints would best be resolved through a meet-and-confer discussion with the agencies themselves. In the meantime, the prosecution offers the following responses based on the information available to it.

1. CMS's Use of Date Restrictions

Defendants object to CMS's use of date restrictions to focus the agency's search for responsive documents. The Court should disregard this objection for several reasons. *First*, the agency has made a good faith determination that this date range appropriately captures the documents responsive to Defendants' requests. The agency arrived at that date range based on its discussions with defense counsel and its knowledge regarding its interactions with Theranos. The agency believes that its responsive documents from the time period before September 1, 2013 have already been captured and produced in its previous productions. Defendants have presented insufficient reason to doubt the agency's judgment regarding how best to locate and produce responsive documents.

Second, the government understands that Balwani's counsel were agreeable to this date range when meeting and conferring with CMS regarding the agency's response to Balwani's subpoena in the SEC civil case—a subpoena seeking a broad range of documents of which the six categories here are a subset. That meet-and-confer process stalled when the parties could not reach agreement on other terms, but Balwani's apparent satisfaction with that date range in the civil case undercuts any complaint by Defendants now.

Third, and finally, CMS has always been transparent with the parties and the Court that it intended to rely on this date limitation in responding to the government's document requests. The agency's July 12, 2019 letter prominently featured that date range, expressly stating that CMS intended to limit its search for documents between September 1, 2013 and December 31, 2016. In fact, the Court quoted that portion of CMS's letter in noting the agency's agreement to diligently search for and produce responsive documents. In previous proceedings, Defendants offered no compelling reason for CMS to deviate from this date range. To the extent Defendants did object, the Court's July 19, 2019

Order citing CMS's date range can be read as implicitly overruling those objections.

Regarding FDA, defense counsel complained that the agency's letter does not specify whether it also relied on a date restriction in collecting and producing documents. The prosecution has subsequently confirmed with agency counsel that FDA, like CMS, faithfully applied the date range that it disclosed in its earlier letter to the parties, that is, January 1, 2010 through June 30, 2018.

2. FDA Redactions

Without citing specific examples, Defendants also have objected to certain redactions contained in FDA's production. Defendants have not shown, however, that FDA withheld any responsive, discoverable information. In FDA's July 9, 2019 letter, the agency explained that it could not produce certain categories of information including third-party trade secret and confidential commercial information. That letter also stated that FDA intended to withhold or redact attorney-client communications, attorney work product, and personal / private information. That FDA followed through on these plans should not come as a surprise to Defendants.

Since learning of Defendant's complaint, government counsel has consulted with FDA counsel regarding the bases for the redactions in the agency's production. Agency counsel, in turn, has informed the government that it redacted information in the following categories: (1) attorney-client / work product; (2) non-Theranos-related deliberative process privileged information; (3) personal privacy information; (4) third-party (non-Theranos) trade secret and confidential commercial information; and (5) non-responsive information wholly unrelated to Theranos. These categories appear to be appropriate bases for redaction, they are consistent with FDA's previous statements regarding its plan for production, and they do not violate the Court's July 19 Order. Defendants have not advanced any substantive arguments to the contrary. Indeed, Defendants are in no position to argue—much less prove—that FDA improperly redacted without first discussing those redactions with the agency and gathering additional information regarding the nature of the withheld information. A meet and confer between defense counsel and agency counsel seems a reasonable next step to address any such concerns. The Court should decline to require any further action on FDA's part at this time.

3. Disclosure of Custodians and Search Terms

Finally, Defendants complain that they are unable to judge the agencies' compliance with the

government's requests and the Court's order because they do not have information regarding the identities of the custodians from whom the agencies collected or a list of any search terms the agencies used to identify responsive documents for review. But Defendants provide no authority for the proposition that they are entitled to know the specifics of the agencies' collection efforts, or to dictate the exact steps the agencies take to respond to the government's document requests and the Court's order. FDA's July 9 letter provided the parties with information regarding the large number of custodians from whom it was collecting. That letter also referenced the agency's plans for avoiding duplication of prior work and for prioritizing review of materials from the custodians most likely to have documents responsive to Defendants' requests. Substantively, Defendants have made no showing that the agencies did not use their best efforts to execute those plans and comply with the document requests at issue. And even if the agency documents were covered by Rule 16 or *Brady*—and they are not—those rules do not support Defendants' current demands for even more details regarding the agencies' collection methods. Under these circumstances, Defendants should accept the agencies at their word as the Court did in its July 19 Order.

Moreover, it bears noting that Defendant's Motion relies heavily on the argument that FDA and CMS previously produced documents in response to the prosecution's requests during the criminal investigation. According to Defendants, the fact that the government was previously able to obtain these materials establishes the government's full access to all agency documents. (*See* Mot., Dkt. No. 67, at 12-13). But when the prosecution made those original document requests, it left it to the agencies to make their own determinations about the mechanics of collecting and producing responsive documents. Through discussions with the prosecution and the agencies themselves, Defendants have been significantly more involved in the specifics of the agencies' recent production. Thus, if Defendants' rights to obtain agency documents depend on the prosecution's degree of access, those rights have been fully satisfied.

To the extent this issue requires any further action from the agencies, the first step should be a meet-and-confer discussion between defense counsel and the agencies rather than an order from the Court.

/ /

II. Defendants' Statement

The Court's July 19, 2019 Order was clear. It required the FDA and CMS to advise the Court by September 23, 2019 "whether they anticipate completing their productions by the" October 2, 2019 deadline. Order at 5, ECF No. 111. The Order also required the FDA and CMS to keep the prosecution "reasonably apprised of the status of their productions" before that interim report, and that the prosecution "shall share such information with Defendants." *Id.*[1] The agencies have made a series of rolling productions with a small number of documents. Until their September 23 letters, however, the agencies and the prosecution have kept the defense almost entirely in the dark on the status of their overall production efforts or the steps the agencies had taken to ensure timely and complete compliance with the Court's order, information which was required to be shared with the Defendants by the Court's Order. And the agencies' September 23 letters raise more questions than they answer.

As an initial matter, neither agency pledges in its September 23 letter that it will be in compliance with the Court's order by the October 2, 2019 deadline. Rather, the FDA letter speaks of "substantial compliance" and CMS similarly does not commit to completing its productions by the deadline. In fact, the agencies' representations regarding the status of their productions continue to be cryptic and artfully worded, and only underscore the continued and pressing need for a Rule 16 order to ensure that all responsive documents are produced to the Defendants by making the DOJ directly accountable. Indeed, even the small production of 2,249 documents by the FDA, the total from the FDA during the two months since the last hearing, contains highly significant *Brady* material that directly contradicts Paragraph 12 of the Superseding Indictment. The DOJ has the experience, obligation, and should have the responsibility to ensure that all agency documents are carefully reviewed for *Brady* as the Court has made clear that the government's "constitutional responsibility under Rule 16 … remains."[2] The government is *not* "off free from anything."[3]

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[1] The defense's motion established that the government has knowledge of and access to the materials and therefore obligations under Rule 16 and *Brady* to produce this material. *See* Dkt. 67; *United States v. Bryan*, 868 F.2d 1032, 1036 (9th Cir. 1989); *United States v. Santiago*, 46 F.3d 885, 893-94 (9th Cir. 1995).

[2] Transcript of Proceedings Before the Honorable Edward J. Davila (July 16, 2019), at 40:6-17.

[3] *Id.* at 40:15-16.

In addition, both agencies report that the bulk of the documents they intend to produce under the Order have not yet been produced to the defense. That is especially true of CMS, where the estimated number of outstanding documents dwarfs the number that it has produced by a factor of more than four. Moreover, the number of documents and pages produced quoted in their letters overstates the breadth of those productions. In the case of the FDA, large swaths of documents have been redacted as not responsive, often excising the context necessary to understand the communication, and many other documents appear to be Google alerts and similar non-substantive emails. The FDA has also failed to produce a log of the "public" documents the FDA is withholding, despite the fact that this very issue was discussed with the Court at the last hearing.[4] Further, a preliminary review of what has been produced suggests substantial gaps, including documents missing from key FDA custodians. To give one example, the FDA has not produced any communications before December 2013, and the vast majority of the communications produced by the FDA thus far were created in the mid-to-late 2015 time period. *See* **Exhibit C** (Histogram of 1,754 Emails Produced to Defendants by FDA). This is very surprising in view of the very frequent interaction between the FDA and Theranos throughout at least the period 2012 through 2016. The FDA's productions so far also do not appear to include any internal FDA documents discussing the lead-up to the FDA's August 2015 inspection, as the Defendants would have expected.

An even larger issue, however, is that the defense is not in a position to assess whether the agencies have complied with the Court's Order when the majority of the documents have not yet been produced. And that is not anticipated to occur until *after* the deadline set by the Court. Likewise, the defense also lacks any information about how the agencies conducted their searches. What search terms did they employ? From which custodians were documents collected? How did they go about collecting documents from these custodians? The agencies' September 23 letters, though they contain many words, do not communicate any of this useful information. Critically, for all their verbiage, the letters do not answer a simple question that Defendants have been asking for months: do the agencies intend to produce *all* documents responsive to the Motion and the Court's orders? The September 23 letters

[4] *See* Transcript of Proceedings Before the Honorable Edward J. Davila (July 16, 2019) at 22:21-23:18.

suggest that their answer would be no. And by when? These unanswered questions only underscore the need for the DOJ to ensure that all responsive documents are produced and certify to the Court that the DOJ's Rule 16 and *Brady* obligations have been met.

CMS, for example, has unilaterally selected a time period starting on September 1, 2013 on the basis that CMS believes a range with this starting point will "reasonably capture[]" documents responsive to the Motion and Order. But the requests in the Motion and Order do not contain a date cutoff, and Ms. Holmes made clear in her pleadings that CMS likely has responsive documents dating back to at least 2012 given that Theranos's CLIA certification began in June 2011. Any production based on this timeline would not include all responsive documents under the Court's Order. CMS's unilateral narrowing of the scope of the request also stands in direct contravention of the Court's comments in the June 28, 2019 hearing when the Court stated that the agencies do not get to make determinations of relevance and usefulness in responding to the requests in the Motion. This unilateral action raises questions of responsibility and accountability for this discovery previously identified in the Motion and at oral argument.

The government suggests that the Defendants have somehow agreed to CMS's narrowing of the relevant time period. Absolutely not. Ms. Holmes did not participate in negotiations that took place in the SEC action to which she is not a party, and has previously demonstrated that responsive documents likely would be found at least back to 2012. Any negotiations that occurred regarding the appropriate date range to apply to CMS's searches for documents occurred in Mr. Balwani's case against the SEC and were never finalized. The DOJ's attempt to cherry pick communications in the SEC case in order to skirt its Rule 16 and *Brady* obligations is inappropriate.[5]

In sum, the defense cannot assess the agencies' efforts at compliance with the Order based on their concededly incomplete productions and cryptic correspondence, but the information the agencies have provided raise serious concerns that these productions are far from complete. The Court can cut through the fog that these letters engender. The Court should hold the DOJ directly accountable to

[5] The Court's order did not "implicitly overrule[]" any objection to a limited date range. The order noted that the productions should include "all documents responsive to the six categories of documents described above, *i.e.*, the six categories stated in Defendants' Motion." Order at 5.

answer the simple question at the core of this dispute: can the prosecution team represent that they are (or soon will be) in full compliance with the Court's order by producing *all* responsive documents in their possession? Because the DOJ has not yet assumed accountability, the Court should also require the agencies' attorneys to attend the October 2, 2019 hearing to explain when they will be in full compliance with the Court's Order.

Time for compliance grows short. A trial date lurks. We are weeks beyond an agreed upon deadline for full Rule 16 production. These agencies are nowhere near providing the documents the defense needs. While DOJ's pleas of distance from the process are designed to spare it from ensuring compliance, that will not save the trial from prejudicial error. The Court should order the DOJ to assume accountability for the full production so that it can certify when the government agencies have fully complied with the Order.

DATED: September 30, 2019

Respectfully submitted,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s/
JEFF SCHENK
JOHN C. BOSTIC
ROBERT S. LEACH
Assistant United States Attorneys

DATED: September 30, 2019

/s/
KEVIN DOWNEY
LANCE WADE
Attorneys for Elizabeth Holmes

DATED: September 30, 2019

/s/
JEFFREY B. COOPERSMITH
STEVE CAZARES
Attorneys for Ramesh "Sunny" Balwani

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

September 23, 2019

Sent By Email
John C. Bostic
Assistant United States Attorney
Northern District of California
150 Almaden Boulevard, Suite 900
San Jose, California 95113
John.Bostic@usdoj.gov

Re: Document Access Request - *United States v. Elizabeth Holmes and Ramesh Balwani*, 18-CR-00258 EJD

Dear Mr. Bostic:

This letter responds to the Court's July 19, 2019 Order in the above-captioned action instructing the Centers for Medicare & Medicaid Services (CMS) to advise the Prosecution no later than September 23, 2019 whether the agency anticipates completing its production of all documents responsive to the six categories of documents described in that Order by the October 2, 2019 deadline.

CMS anticipates producing all documents responsive to the six categories that are not protected by the attorney-client or work product privileges by the deadline or shortly thereafter. Specifically, CMS produced a total of 2,688 responsive documents to the parties on July 31, 2019 and September 20, 2019. In addition, CMS collected the remaining responsive documents, completed its attorney-client privilege review, and submitted a request to DOJ's Litigation Technology Service Center (LTSC) today to prepare those documents for production. The agency anticipates that this production will include 11,200 responsive documents. The LTSC has not yet provided an estimate of when the production will be ready, but these requests typically take approximately ten work days to prepare. CMS will provide you with an estimated production date as soon as we hear from the LTSC.

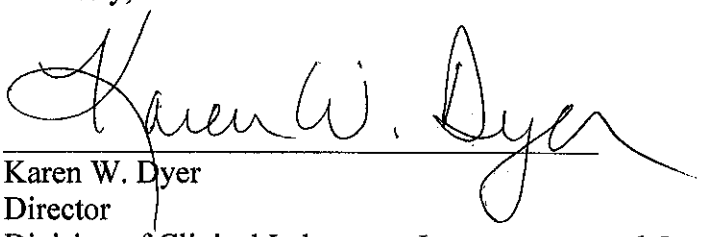
To identify documents responsive to the six categories, CMS used the time period September 1, 2013 through December 31, 2016. This time period was proposed, and agreed to, by Mr. Balwani's counsel to narrow the time period relevant to Mr. Balwani's subpoena to CMS in *SEC v. Balwani*, Case No. 18-cv-01602-EJD. The agency determined that this time period reasonably captured all CMS documents responsive to the six categories at issue in the criminal case. All of the key events occurred within this period. For example, Theranos's application for CLIA certification (CMS Form 116) was signed by the Theranos laboratory director on November 24, 2013 and the first CLIA survey of a Theranos laboratory was conducted by the California Department of Public Health, Laboratory Field Services on December 3, 2013. The CMS 2567 Statement of Deficiencies and Plan of Correction was issued the same day. Further supporting this time period limitation, Theranos notified CMS on October 5, 2016 that it had decided to close the Newark, California and Scottsdale, Arizona laboratories and surrender its CLIA certifications.

As previously explained, CMS does not have documents responsive to Request No. 5. While CMS interacts with and supports law enforcement, the agency does not serve a criminal law enforcement function and, therefore, it does not create or retain Reports of Investigation (ROIs) memorializing government communications with witnesses.

Given the October 2nd deadline for document production contained in the Court's July 19, 2019 Order, CMS had limited time to review the potentially responsive documents before production. As a result, non-responsive, privileged, or otherwise protected information, including deliberative internal communications that are not about Theranos, may be included in the CMS productions to the parties. The production to the United States, Holmes, and/or Balwani of non-responsive, privileged, or otherwise protected information in CMS's documents, including but not limited to deliberative internal communications that are not about Theranos contained in such documents, whether knowing or inadvertent, will not be considered a waiver of any privileges or protections that CMS may have with regard to such documents or information.

Please contact CMS counsel Lindsay Turner if there is a need to discuss this matter further.

Sincerely,



Karen W. Dyer
Director
Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services

EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 23, 2019

Via Email

John C. Bostic
Assistant United States Attorney
john.bostic@usdoj.gov

Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear John:

Pursuant to the Court's July 19, 2019 Order, this letter is to advise you of the status of the U.S. Food and Drug Administration's ("FDA") production of documents responsive to Defendants' motion to compel in the above-referenced case.

FDA has taken great efforts to meet the Court's October 2, 2019 deadline and barring any unforeseen personnel or technical issues, it anticipates that it will be in substantial compliance with that deadline, as detailed further below. As you know, since the Court's Order, FDA has made four productions to the parties totaling over 2,400 documents / 25,000 pages. FDA also expects to make a substantial production to the parties on or before October 2 of approximately 2,530 documents. The number of documents and pages is likely to be more, as approximately 500 additional documents marked as responsive and non-privileged, are currently undergoing second-level review.

Following the Court's July Order, FDA continued its manual review and production of documents while, at the same time, it investigated access to technology-assisted methods to facilitate its review. Through a special arrangement with its parent agency, the U.S. Department of Health and Human Services, FDA was able to obtain access to an electronic document review platform and has, since August, been using that platform to de-duplicate, review, and ultimately produce documents responsive to the motion to compel. This has helped to streamline this massive review: for example, out of 151,180 documents from over 65 custodians collected in response to the subpoena issued in the SEC matter, 75,181 were identified via metadata as exact duplicates.[1] Additionally, FDA was able to segregate the remaining documents into the following two buckets:

[1] For example, if email A was sent to Persons 1, 2, and 3, the platform was able to automatically determine that email A for Person 1 should be loaded for review (and list Persons 2 and 3 as additional custodians) without actually loading three copies of email A to the database for review, thereby cutting the review time for email A by two-thirds.

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

1) Documents potentially responsive to the motion to compel categories that appeared to be unique[2]: 4,602
2) Documents potentially responsive to the motion to compel categories that, via a textual analysis, appear to be duplicates of documents already in the possession of the parties because of prior productions of FDA documents, or duplicates of each other[3]: 39,803

Since bucket one contains documents that appear to be distinct from those previously produced, FDA has made review and production of documents from that bucket its top priority. As explained above, of the 4,602 documents in bucket one, FDA expects that the parties will receive as many as 3,000 responsive, non-privileged documents on or before October 2.

While the FDA has been focusing its efforts on bucket one, it has also been reviewing bucket two in an effort to identify any non-duplicate documents in that bucket. Based on the progress to date, FDA has already eliminated 32,470 of the documents in the second bucket as duplicates. 7,333 remain in further de-duplication or responsiveness review. Many of these documents, while not exact duplicates of previously produced documents, are so similar to each other or previously-produced documents that they actually provide no new substantive information. Nonetheless, as FDA identifies unique documents (even those that actually provide no new substantive information), those documents are added to the review population. FDA is aiming to produce the responsive, non-privileged documents from this 7,333 subset on or before October 2.

Although it is difficult for FDA to determine at this point how many responsive, non-privileged documents will remain to be produced after October 2, if FDA is not able to produce all responsive, non-privileged documents from current bucket two by that time, the number left to produce should be no greater than what remains in that bucket, i.e., 7,333. Notably, the number is likely to be substantially fewer than that due to continued efforts to de-duplicate documents from the second bucket and as a result of responsiveness and privilege review.

It is likely that the following sets of documents will not be included in FDA's October 2 production:

- Documents from FDA's Office of the Chief Counsel, on the basis that all, or the vast majority, of the documents not already captured in productions from other custodians are protected by the attorney-client privilege and/or work product doctrine;
- Documents identified as containing foreign language or technical issues, such as stub files (i.e. archived files that need to be restored from FDA's network, re-loaded to the platform, and then reviewed);
- A subset of documents from two custodians who were former employees, due to technical difficulties during collection. Among other issues, a corrupt Outlook

[2] Not including documents from FDA's Office of the Chief Counsel
[3] Not including documents from FDA's Office of the Chief Counsel

FDA U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
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Data File (".pst file") needed to be repaired; emails needed to be located in backup tapes and restored prior to searching; and a data collection system crashed. Notably, though, these technical difficulties affected only (a) one of eight .pst files from one custodian (the other seven were transferred to the review platform), and (b) a subset of documents for another custodian, who FDA believes is unlikely to have documents responsive to the motion to compel.

FDA has devoted extensive resources to this review in an effort to meet the Court's deadline and believes that, with the documents that it will produce on or before October 2, the parties will have received the vast majority of information responsive to the Court's July 19, 2019 Order. The review undertaken to date demonstrates that any remaining documents that FDA will continue to work on after October 2 are unlikely to contain novel information, even if they are not exact duplicates of previously produced documents. The primary reason that FDA anticipates that it will not be in strictly full compliance (rather than substantial compliance) with the Court's October 2 deadline is primarily due to the sheer volume of the data and the delay caused by having to retrieve backups of damaged files. FDA, of course, understands the time sensitivities for the parties, and thus will continue its diligent efforts to review and produce responsive, non-privileged documents. Barring further technical difficulties, FDA anticipates that it can complete its document production in this matter by approximately October 28.

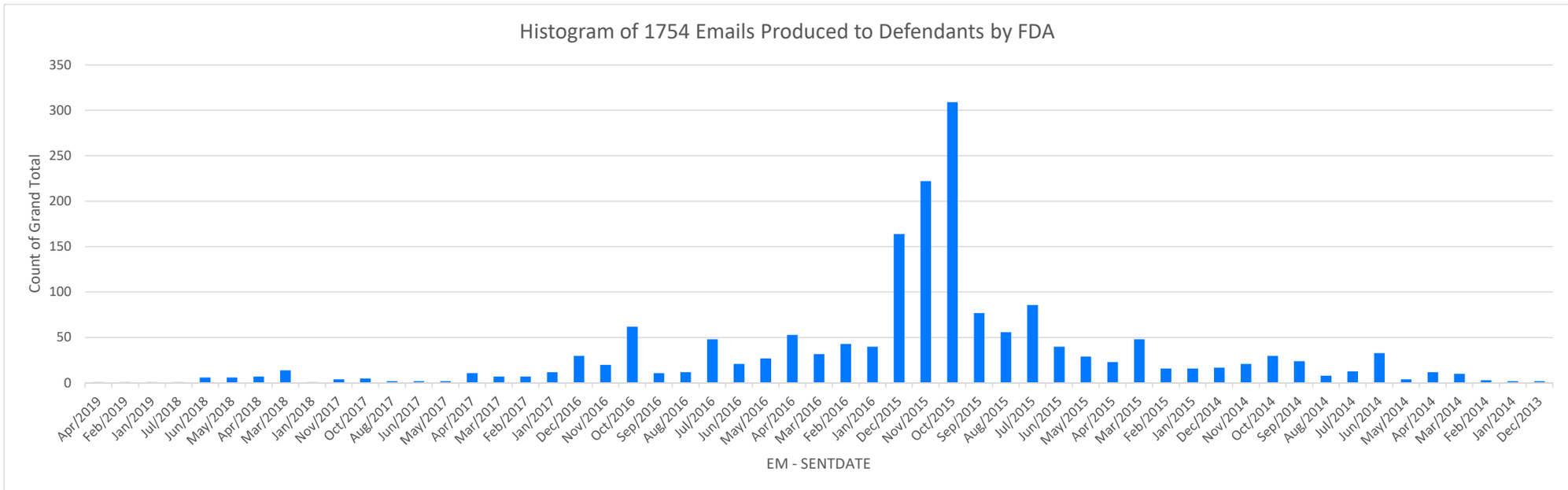
I trust that this letter provides you with the information required by the Court's July 19, 2019 Order. FDA will continue to work as expeditiously as possible to provide the parties with the documents subject to the Court's Order, as set forth above.

Sincerely,

Marci B. Norton AMK

Marci B. Norton
Senior Counsel

EXHIBIT C


Histogram of 1754 Emails Produced to Defendants by FDA
Count of Grand Total
350
300
250
200
150
100
50
0
Apr/2019
Feb/2019
Jan/2019
Jul/2018
Jun/2018
May/2018
Apr/2018
Mar/2018
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Nov/2017
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Nov/2017	4
Oct/2017	5
Aug/2017	2
Jun/2017	2
May/2017	2
Apr/2017	11
Mar/2017	7
Feb/2017	7
Jan/2017	12
Dec/2016	30
Nov/2016	20
Oct/2016	62
Sep/2016	11
Aug/2016	12
Jul/2016	48
Jun/2016	21
May/2016	27
Apr/2016	53
Mar/2016	32
Feb/2016	43
Jan/2016	40
Dec/2015	164
Nov/2015	222
Oct/2015	309

Sep/2015	77
Aug/2015	56
Jul/2015	86
Jun/2015	40
May/2015	29
Apr/2015	23
Mar/2015	48
Feb/2015	16
Jan/2015	16
Dec/2014	17
Nov/2014	21
Oct/2014	30
Sep/2014	24
Aug/2014	8
Jul/2014	13
Jun/2014	33
May/2014	4
Apr/2014	12
Mar/2014	10
Feb/2014	3
Jan/2014	2
Dec/2013	2
Grand Total	1,754

Mar/2017	7
Feb/2017	7
Jan/2017	12
Dec/2016	30
Nov/2016	20
Oct/2016	62
Sep/2016	11
Aug/2016	12
Jul/2016	48
Jun/2016	21
May/2016	27
Apr/2016	53
Mar/2016	32
Feb/2016	43
Jan/2016	40
Dec/2015	164
Nov/2015	222
Oct/2015	309
Sep/2015	77
Aug/2015	56
Jul/2015	86
Jun/2015	40
May/2015	29
Apr/2015	23
Mar/2015	48
Feb/2015	16
Jan/2015	16
Dec/2014	17
Nov/2014	21
Oct/2014	30
Sep/2014	24
Aug/2014	8
Jul/2014	13
Jun/2014	33

May/2014	4
Apr/2014	12
Mar/2014	10
Feb/2014	3
Jan/2014	2
Dec/2013	2
Grand Total	1,754